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Fax 312/489-7744**NOV 1 1996**Heelbo, Inc.
Pelvic Restraint**Safety and Effectiveness Summary****1. Submitter's name, Address and Contact Person**SubmitterHeelbo, Inc.
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2. Name of Device:

Heelbo Pelvic Restraint

3. Name of Predicate Device(s)

Heelbo Pelvic Restraint

4. Description of Device

The Heelbo Pelvic Restraint is constructed of polyester mesh. Straps sewn onto both sides of the front panel and back panel are used to secure the patient to the wheelchair or geriatric chair. A catheter access slot has been incorporated into the restraint design for those patients that utilize an indwelling catheter.

The Pelvic Restraints are available in three sizes, small, medium and large to accommodate a wide range of patients. The Pelvic Restraints are machine washable for continued use.

5. Statement of Intended Use

The Heelbo Pelvic Restraint is intended to help secure a patient while seated in a wheelchair or geriatric chair.

6. Statement of Technological Characteristics of the Device

The Heelbo Pelvic Restraint is constructed of polyester mesh. Straps sewn onto both sides of the front panel and back panel are used to secure the patient to the wheelchair or geriatric chair. A catheter access slot has been incorporated into the restraint design for those patients that utilize an indwelling catheter.

Heelbo, Inc.
Pelvic Restraint

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The subject devices are identical in intended use, design, materials, manufacturing process, physical and mechanical specifications and issues of safety and effectiveness to the devices prior to the submission of this notification. The only difference is that the product labeling has been revised to comply with the Agency's labeling requirements set forth in the draft "Guidance on the Content of Premarket Notification [501(k)] Submissions for Protective Restraints" dated December 1995.

7. Biocompatibility

The subject devices are identical in component materials to the predicate devices. The suppliers of the materials use in the fabrication of these devices have stated that there is a history of safe use of their materials in the clothing and garment industry. In addition, Heelbo, Inc., is not aware of any reports or complaints of skin irritation associated with these materials.

8. Conclusion

Based upon the information presented above it is concluded that the proposed Heelbo Pelvic Restraint is safe and effective for its intended use and is substantially equivalent to the predicate device.